



H.R. 3580 – The Food and Drug Administration Amendments Bill

FLOOR SITUATION

H.R. 3580 is being considered on the floor under suspension of the rules and will require a two-thirds majority vote for passage. This legislation was introduced by Representative John Dingell (D-MI) on September 19, 2007 and not been considered by any Committee in the 110th Congress.

**Note: The language contained in H.R. 3580 is a combination of language from H.R. 2900 the Food and Drug Administration Amendments Act of 2007, which passed in the House of Representatives by a vote of 403 - 16 ([Roll no. 617](#)) on July 11, 2007, and language contained in S. 1082 the Food and Drug Administration Revitalization Act, which passed in the Senate by a vote of 93 - 1. [Record Vote Number: 157](#) on May 9, 2007.*

H.R. 3580 will be considered on the floor of the House of Representatives on September 19, 2007.

SUMMARY

H.R. 3580:

Title I - Prescription Drug User Fees

- Reauthorizes the FDA's ability to collect a slate of user fees to be collected from prescription drug manufacturers to generate a total sum of \$392.8 million in FY2008, and another \$225 million over the next 5 years. The fees are used to fund various programs including consideration of new drug applications and strengthening and maintaining drug safety. Federal funds for post market safety programs and user fees levied on private companies are balanced by a "reverse trigger" mechanism in the bill that requires a dollar for dollar reduction in new user fees for every new dollar appropriated, on top of inflation-adjusted current levels, for post market safety.
- Exempts manufacturers of orphan drugs (see background section for definition) from any product and facility fees.
- Establishes a new program to assess, collect, and use fees for the voluntary review of prescription drug direct-to-consumer (DTC) television advertisements.

**Note: The current program for collection of fees as it relates to new drug and biologic applications for the voluntary review of DTC television ads expires at the end of FY2007.*

Title II - Medical Device User Fees

- Reauthorizes the FDA to collect user fees from medical device manufacturers that apply for FDA approval for a device up to \$287 million over the next 5 years.
- Authorizes \$35.5 million over the next 5 years for collecting, developing, reviewing, and evaluating post-market safety information on medical devices.

**Note: The authorization allows this appropriation to be increased by inflation over the 5 years.*

- Establishes two new annual fees on medical device manufacturers for registering with the FDA and a fee for filing periodic reports for devices that have received FDA approval to provide information on manufacturing and design changes and new studies involving their products. This has the effect of lowering user fees for medical device applications.
- Requires the Comptroller General to conduct a study on the number of healthcare-related infections that are attributable to new and reused medical devices and the causes of those infections and to report to Congress within one year of the date of enactment of this bill.
- Establishes procedures to streamline and improve the third-party inspection program for medical device manufacturing facilities.

Title III - Pediatric Medical Device Safety

- Requires that an application or protocol submitted to the Secretary for a device must include a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients.
- Modifies the existing Humanitarian Device Exemption to allow companies to make a profit for devices specifically designed to meet a pediatric need. Under no circumstances can there be a profit on sales if the device is used to treat or diagnose diseases or conditions affecting more than 4,000 individuals in the U.S. per year (same as current law).
- Requires adverse events for pediatric HDE devices to be reported to the Office of Pediatric Therapeutics and requires the Pediatric Advisory Committee to conduct an annual review to determine whether the exemption is still appropriate.

- Requires the Director of the National Institutes for Health (NIH) and the Commissioner of the FDA to develop a plan for expanding pediatric medical device research and development.
- Authorizes \$30 million over the next 5 years for a program to encourage innovation in developing pediatric devices by connecting manufacturers with individuals with device development ideas, mentoring and management projects for pediatric device design and marketing, and services such as business feasibility studies.

Title IV - Pediatric Research

- Reauthorizes for five years, the FDA's authority to require a manufacturer of a drug or biologic who submits an application to market a new active ingredient, new form of dosage, new dosing regimen, or a new means of administering the drug or biologic to submit an assessment of the drug's or biologic's effects on pediatric patients if appropriate.

**Note: The current authorization for this program is set to expire at the end of FY2007.*

Title V - Studies of Pediatric Drugs

- Reauthorizes for five years the FDA's authority to grant an additional six months of market exclusivity to drug manufacturers in return for completion of FDA-requested pediatric use studies and reports.
- Authorizes the Secretary of HHS to award grants for pediatric research for products whose patents have expired or for products whose manufacturer declines to conduct FDA-related studies.
- Requires the NIH and FDA to conduct a study to develop a priority list of needs in pediatric therapeutics, diseases, and disorders that require further study and authorizes NIH to award funds to entities to conduct pediatric clinical trials or other research in the priority areas.

Title VI - Reagan-Udall Foundation

- Establishes a non-profit organization for the purpose of advancing the mission to modernize medical, veterinary, food, food ingredient, and cosmetic product development, as well as working to accelerate innovation and enhance product safety.
- Requires the foundation to set goals and priorities to meet its mission and authorizes the foundation to award grants with qualified individuals and organizations to conduct research in these fields to meet the unmet needs in the areas of the foundation's mission.

- Requires the FDA to provide funding for the foundation with transfers of between \$500,000 and \$1.25 million from its appropriated funding each fiscal year.

Title VII - Conflicts of Interest

- Reaffirms the current requirement that prevents individuals with a financial interest, or with any immediate family member with a financial interest in the business before a FDA advisory committee from being members of that committee.
 - Waivers permitting individuals with a conflict(s) of interest to participate as members of an FDA advisory committee: The bill requires that the number of waivers the Secretary may grant permitting individuals with a conflict(s) of interest to be members of a FDA advisory committee must be reduced by 25% over five years from the total number of waivers granted in 2007 (at a rate of 5% a year over five years). Any waivers that are granted by the Secretary must be made public within fifteen days of the meeting of the advisory committee meeting and must be posted on the internet.

**Note: This is new language that was not contained in H.R. 2900 and it replaces a provision of H.R. 2900 that permitted the Secretary to grant no more than one waiver to this conflict of interest rule per committee meeting.*

Title VIII - Clinical Trial Databases

- Requires NIH to establish and administer a database of a registry of clinical trials in progress and separate database for clinical trial results. These databases are to be made publicly available on the internet and searchable and would contain information on both publicly funded and privately funded clinical trials.
- Imposes penalties of up to \$15,000 for individuals or organizations that are found to be in violation of the regulations regarding submission of clinical trial information to the appropriate databases.

Title IX - Postmarket Drug Safety

- Authorizes the Secretary of HHS, if he/she becomes aware of new drug safety information, to require the recipient of FDA approval for a drug to conduct a post-approval study or trial to assess or identify any risks of using the drug and to report back to the Secretary at regular intervals on an established timeline.
- Authorizes the Secretary of HHS to require drug companies to change the labeling of a drug if the Secretary deems it appropriate in light of new safety information.
- Authorizes the Secretary to require a “Risk Evaluation and Mitigation Strategy” (REMS) to ensure that the drugs benefits outweigh its risks. Such a risk evaluation and mitigation strategy could include a plan to communicate the risks

of the drug with healthcare providers and drug consumers or restricted distribution of the drug.

- Directs the Secretary to develop an active surveillance system for better monitoring and identifying any potential risks for drugs after they have been approved and are on the market.
- Establishes civil penalties:
 - For individuals that disseminate false or misleading drug advertisements, the penalties can be assessed at up to \$250,000 for the first violation in any 3-year period, and up to \$500,000 for each subsequent violation in any 3-year period.
 - For drug companies that fail to comply with the requirements of their approved risk evaluation and mitigation strategy (REMS) of up to \$250,000 per violation, and up to \$1 million for all violations adjudicated in one proceeding. Violations that continue after the violating company has been notified may be fined up to \$250,000 for the first 30 days, and the fine shall double every 30 days thereafter up to \$1 million for a 30 day period and up to \$10 million for all such violations adjudicated in one proceeding.
- Citizen Petitions: The bill establishes that the FDA cannot delay approval of an application on the basis of a citizens' petition, unless the delay is based on the protection of the public health. The bill requires that the filer of the petition must certify, under the penalty of perjury, that the information contained in the petition is full and accurate. Further, the legislation requires the FDA to act on a citizens' petition within 180 days of filing and requires the filer to wait 180 days after filing before they can challenge the drug approval in court.

Title X – Food Safety

- Requires the Secretary of HHS to establish a registry of food that may be adulterated and pose a significant health risk, the registry will create a record for HHS to track problems and respond.
- Requires the Secretary of HHS to establish regulations that set standards for labeling, processing, and ingredient definitions for pet food.

**Note: The language included in this title was not included in the House passed bill, H.R. 2900.*

Title XI – Miscellaneous

- Establishes a system of incentives, including market exclusivity and priority consideration, for certain drugs that affect global populations that may not otherwise have sufficient market incentives to bring them to production. One incentive the bill creates to reward producers and developers of these drugs and devices is a voucher that they may be awarded that provides for priority review of a drug or device and may be sold to other drug and device makers and developers.

**Note: The language included in this title was not included in the House passed bill, H.R. 2900.*

BACKGROUND

The FDA is responsible for evaluating drugs before they can be marketed in the United States, in order to gain approval a drug manufacturer “must demonstrate the drug's safety and effectiveness to FDA's satisfaction, see its manufacturing plant pass FDA inspection, and obtain FDA approval for the drug's labeling -- a term that includes all written and electronic material about the drug, including packaging, prescribing information for physicians, and patient brochures.”

The drug approval process begins with the manufacturer submitting a request to begin clinical trials, which if approved, proceeds in three phases. If the clinical trials are successful, the manufacturer may submit a “new drug application” which requires the manufacturer to detail all data on the drug as well as such information as how the drug will be manufactured and labeled.

The next step in the approval process is an extensive review where the FDA has 180 days to process the new drug application but if the FDA discovers any deficiencies, the clock stops, and the manufacturer submits additional information. “If the drug is approved then the FDA initiates its *post-market* regulatory procedures. Manufacturers must report all serious and unexpected adverse reactions to FDA and clinicians and patients may do so.” ([CRS: RL32797](#))

Orphan Drugs

According to the FDA’s Office of Orphan Products Development (OOPD), orphan drugs are defined by the Orphan Drug Act as drugs developed to treat rare diseases.

COST

A cost estimate on H.R. 3580 was not available from the Congressional Budget Office (CBO) at the time of publication.

STAFF CONTACT

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